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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/923,270 | 08/03/2001 | Jurgen Kleinschmidt | 8484-101-999 | 3472 |

7590 03/11/2003

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[REDACTED] EXAMINER

WINKLER, ULRIKE //

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1648

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------------|---------------------|
| Office Action Summary | Application N . | Applicant(s) |
| | 09/923,270 | KLEINSCHMIDT ET AL. |
| | Examiner | Art Unit |
| | Ulrike Winkler, Ph.D. | 1648 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 13-27 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 13-27 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 - Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 - If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. The Office also acknowledges receipt of the certified translation of 196 44 500.0 (25 October 1996).

Specification

Applicant is required to update the status (pending, allowed, abandoned, ect.) of all parent priority applications in the first line of the specification.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, Paper No. 1, is attached to the instant Office Action.

Drawings

The drawings are objected to, please see Notice of Draftsperson's Review attached to the instant Office Action. Correction is required.

Applicant is reminded of the new changes to the drawing requirements on the attached Notice of Draftsperson's Review. Applicant is required to submit the drawing corrections within the time period of response set in the instant office action (see 37 CFR 1.85(a)).

The lettering in the figures is too small. It is nearly impossible to make any of the letters, enlarging the print would help clarify the figure and make them more legible.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. While the office appreciates that applicant may be his or her own lexicographer, a term must still be clearly defined. In the instant application an AAV DNA is defined as any AAV DNA which may contain helper virus sequences necessary for developing viral particles (page 2, lines 27-30). "Helper virus sequences" is defined (see page 2 line 28 to page 3 line2) as herpes virus and/or adenoviruses more particularly from adenovirus type 5. The sequences may comprise the entire adenovirus genome or a fragment. The claims are drawn to AAV helper virus (which according to the definition in the specification would be herpes virus and/or adenoviruses) the claims then go to define the AAV helper virus to be an "AAV 5" the ordinary artisan would interpret this to be an adeno associated virus type 5 with the exception of E1 region (claim 13) or the L1 and E1 region (claim 15). The term "with the exception" is interpreted as being deleted. Because adeno associated viruses (AAV) comprises ITR's rep and cap but do not comprise an E1 or L1 region one of ordinary skill in the art would not know what is intended by an "AAV 5 sequence with the exception of the E1 region".

For purposes of claim interpretation the limitation "AAV 5 sequence with the exception of the E1 region" has not been given any weight because it is not clear what is actually included or excluded by the term.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not provide a written description for an “AAV 5” sequence or an “AAV 5 with the exception of the E1 region and/or L1 region”. This is a new matter rejection.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 13, 15, 17, 19, 20, 22, 24, 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Colosi (U.S. Patent No. 6,004,797).

The instant invention is drawn to nucleic acids comprising AAV helper virus sequences and a method of producing rAAV viral particles. The necessary helper virus sequences can be derived from adenovirus, adenovirus 5 and herpesvirus. The instant specification discloses that rAAV is any viral particle and its DNA which may or may not contain foreign DNA (page 3, lines 3-5). AAV DNA is any AAV DNA which may contain helper virus sequences necessary for developing viral particles (page 2, lines 27-30). Because it is not clear what is meant by "AAV 5 sequence" (see above), the claims have been interpreted as reading on helper virus sequences only (such as herpes virus or adenovirus).

The reference of Colosi discloses a method of producing AAV viral particles without using a helper virus (see column 5, lines 5-57). The non-AAV helper virus accessory functions, needed for AAV particle release, can be derived from adenovirus, herpesvirus and vaccinia virus (column 8, lines 29-39, column 17, lines 23-30; claim 10). Therefore, the instant invention is anticipated by Colosi.

Claims 5, 6, 8 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Wang et al. (U.S. Patent No. 5,872,005).

The instant invention is drawn to nucleic acids comprising AAV helper virus sequences and a method of producing rAAV viral particles. The necessary helper virus sequences can be derived from adenovirus, adenovirus 5 and herpesvirus. The instant specification discloses that rAAV is any viral particle and its DNA which may or may not contain foreign DNA (page 3,

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lines 3-5). AAV DNA is any AAV DNA which may contain helper virus sequences necessary for developing viral particles (page 2, lines 27-30). Because it is not clear what is meant by "AAV 5 sequence" (see above), the claims have been interpreted as reading on helper virus sequences only (such as herpes virus or adenovirus).

The reference of Wang et al. discloses a method of producing helper virus free AAV viral particles using a cell line that contains the non-AAV complementing sequences necessary for AAV packaging (columns 7 and 8). Therefore, the instant invention is anticipated by Wang et al.

Allowable Subject Matter

Limiting the claims to the deposited nucleic acids sequences or methods using the deposited nucleic acids sequences would be allowable.

Conclusion

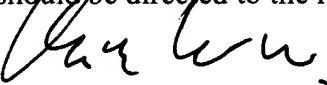
No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Ulrike Winkler, Ph.D. 3/10/03